

September 23, 2019

The Honorable Susan Illston
U.S. District Court for the Northern District of California
450 Golden Gate Avenue, Courtroom No. 1 – 17th Floor
San Francisco, CA 94102

Re: *Illumina, Inc. v. Natera, Inc.*, No. 3:18-cv-01662-SI (N.D. Cal.)

Dear Judge Illston:

NATERA’S POSITION

We write regarding Illumina’s refusal to provide a complete response to Natera’s Interrogatory No. 18 (“ROG 18”), which asks Illumina to identify all facts and documents supporting its position that the claims of the Illumina asserted ’831 patent contain an inventive concept sufficient for patent eligibility under 35 U.S.C. § 101. Last year, in opposing Natera’s Motion to Dismiss, Illumina represented to the Court that the asserted claims include an inventive concept. *See, e.g.*, Dkt. 32 (Illumina’s Opposition to Motion to Dismiss) at 13. Although the Court held at *Mayo/Alice* Step One that the claims are directed to an ineligible natural phenomenon, the Court held at Step Two that the “factual record [was] not sufficient” to determine whether the claims have an inventive concept, and specified categories of facts it needed to assess the issue. Dkt. 41 (Order re Motion to Dismiss) at 6–7.

Over a year has passed, but Illumina has failed to identify any such facts or evidence, including in its response to ROG 18. At bottom, Illumina cannot represent that *facts* exist allegedly supporting an inventive concept but refuse to identify those *facts* and any supporting evidence. Respectfully, the Court should order Illumina to supplement its response to ROG 18, or, alternatively, limit Illumina to the information provided in its original response.

Background

Natera’s Motion to Dismiss. On May 17, 2018, Natera filed a Motion to Dismiss because the ’831 patent claims are not patent-eligible. Dkt. 24. In opposition, Illumina argued that “there is a factual dispute” over whether the claims have an inventive concept. Dkt. 32 at 13–14; *see also* 6/22/18 Hearing Tr. (Motion to Dismiss) at 27:4–10, 31:24–32:1.

At *Mayo/Alice* Step One, the Court held that the claims are directed to a natural phenomenon. Dkt. 41 at 6. The Court denied the motion without prejudice, however, because at Step Two it found that “the factual record is not sufficient . . . to conclude whether there is an inventive concept.” *Id.* at 7. The Court specified that it needed additional facts to determine “whether the amplification of ‘at least 100 different non-random polynucleotide sequences’ and the performance of ‘successive rounds of amplification using primers that are directed to sequences *within* the products of prior amplification reactions’ are routine or conventional,” and also “whether the claimed selective enrichment leads to a technological improvement.” *Id.*

ROG 18. On May 29, 2019, Natera served Illumina with ROG 18, which states: “Describe all factual bases and identify all supporting documents for any contention by [Illumina] that the claims

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of the '831 Patent contain an inventive concept,” including the above-mentioned categories of information that the Court requested. Ex. A (6/28/19 ROG Responses) at 8–9. On June 28, 2019, Illumina provided no substantive response and instead broadly pointed to its Opposition to the Motion to Dismiss (Dkt. 32), as well as a Patent Trial and Appeal Board’s (“PTAB”) decision declining to institute *inter partes* review as to the '831 patent based on prior art that Natera argued rendered the claims obvious under 35 U.S.C. § 103. Ex. A at 8–9.

On August 26, 2019, the parties met and conferred regarding Illumina’s response. Natera explained that the response is deficient because it fails to identify any specific facts or documents allegedly supporting an inventive concept, including the specific categories of information that the Court requested. Natera also explained that the PTAB decision is legally irrelevant because it only addressed the issue of obviousness, which is an entirely separate inquiry from patent eligibility.

On September 5, 2019, Illumina advised that it would not supplement its response, arguing that (1) pages 16–18 and 20 of its Opposition to the Motion to Dismiss contain “over a half-dozen factual *allegations*,” (2) the PTAB decision is relevant to eligibility because the issue overlaps with obviousness, and (3) ROG 18 is premature. 9/5/19 Email from C. Lavin (emphasis added).

Illumina Should Be Compelled to Supplement Its Response to ROG 18

Over a year ago, Illumina represented to the Court that the '831 patent claims contain an inventive concept. But Illumina has since failed—and refuses—to provide any evidence that allegedly supports its arguments of inventive concept.

First, as Illumina acknowledges, the pages of the Opposition to which Illumina points (Dkt. 32 at 16–18 and 20) contain nothing but *allegations*. 9/5/19 Email from C. Lavin. Those pages identify no specific facts, much less evidence, that allegedly support Illumina’s bare allegation of inventive concept. It is well established that attorney argument is not *evidence*. *Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017) (“Attorney argument is not evidence.”). Illumina’s attempts to exaggerate the sparse conclusory citations in its Opposition as setting forth substantial facts and evidence should be rejected.

Second, Illumina’s citation to the PTAB decision is legally irrelevant because it only addressed the issue of obviousness based on certain prior art references. The Supreme Court and Federal Circuit each have repeatedly made clear that patent eligibility “is a ‘threshold test’ that typically *precedes* the novelty or obviousness inquiry,” and thus “is a requirement *separate* from other patentability inquiries.” *Return Mail, Inc. v. U.S. Postal Service*, 868 F.3d 1350, 1370 (Fed. Cir. 2017), *rev’d on other grounds*, 139 S. Ct. 1853 (2019) (emphasis added); *see also Parker v. Flook*, 437 U.S. 584, 593 (1978) (“The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious,” and thus the eligibility inquiry “does not involve the familiar issues of novelty and obviousness that routinely arise under §§ 102 and 103.”). Even if the PTAB decision were relevant, which it is not, Illumina fails to identify the portions of the decision that allegedly show inventive concept.

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Third, Illumina's arguments about document production and upcoming depositions, including the depositions of the '831 patent inventors and Illumina's Rule 30(b)(6) witnesses, only further emphasize why Illumina must identify all facts and evidence regarding inventive concept *now*. Natera is entitled to know what Illumina's facts and evidence are *before* those depositions so that Natera can question relevant witnesses on any such facts and evidence. In addition, Natera's document production will not support any inventive concept for Illumina's '831 patent claims.

Over a year has passed since Illumina asserted that the '831 patent claims include an inventive concept. Opening expert reports are two months away. There is nothing premature about Natera's ROG 18. It is time for Illumina to identify the actual facts and supporting evidence that support its allegation that the claims contain an inventive concept, including that the claims are directed to non-routine and non-conventional subject matter that "leads to a technological improvement" and "amounts to *significantly more* than a patent upon" the ineligible natural phenomenon itself. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012) (emphasis added).

Accordingly, Illumina should be compelled to immediately supplement its response to ROG 18 with all facts and evidence supporting any argument that the '831 patent claims contain an inventive concept, including the categories of information the Court requested in its June 26, 2018 decision on the Motion to Dismiss (Dkt. 41 at 7). Alternatively, Illumina should be limited to its original ROG response as factual support for any such arguments concerning inventive concept.

ILLUMINA'S POSITION

Amidst the parties' bulk exchange of documents and scheduling of depositions, Natera seeks a final answer to a contention interrogatory regarding Natera's patentable subject matter attack on the '831 Patent. Natera bears the burden of proof on this issue and is attempting to shift it to Illumina. Moreover, Natera ignores the quality of the response that Illumina has already provided and that the specific issues of inventiveness, technological improvement and prior art conventionality are appropriately the subject of expert discovery.

Illumina's existing interrogatory response incorporates, among other things, its substantive position on the "inventive concept" issue from its Opposition to Natera's Motion to Dismiss. That document contains an entire section directed to inventive concept that explains that the steps of amplification of "at least 100 different non-random polynucleotide sequences" and the performance of "successive rounds of amplification using primers that are directed to sequences within the products of prior amplification reactions" are not routine or conventional and that the inventive method leads to a technological improvement. *See* Dkt. No. 32 at 18-19.

As explained, the '831 Patent itself addresses the inventive concept:

Methods for randomly enriching fetal nucleic acids in cell-free maternal sample have been described, including enriching nucleic acids based on size, formaldehyde treatment,

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methylation status, or hybridization to oligonucleotide arrays. There is a need for a means of selectively enriching non-random fetal and maternal polynucleotide sequences in a way that facilitates aneuploidy detection by massively parallel sequencing techniques and increases the sensitivity of aneuploidy detection.

Dkt. No. 1-5 at 1:30-39.

Illumina's Opposition also cites to evidence from Natera's own patent filings to support that its invention was a significant improvement and there was need for it in the prenatal diagnostics field:

Use of multiplex PCR can significantly simplify experimental procedures and shorten the time required for nucleic acid analysis and detection. However, when multiple pairs are added to the same PCR reaction, non-target amplification products may be generated, such as amplified primer dimers. The risk of generating such products increases as the number of primers increases. These non-target amplicons significantly limit the use of the amplified products for further analysis and/or assays. Thus, improved methods are needed to reduce the formation of non-target amplicons during multiplex PCR. Improved multiplex PCR methods would be useful for a variety of application, such as Non-Invasive Prenatal Genetic Diagnosis (NPD).

Dkt. No. 1-4 ¶¶ 4-5.

In addition, Illumina's existing interrogatory response identifies as yet another source for supporting evidence the Patent Board's denial of institution of *inter partes* review for the '831 Patent in IPR2018-01317. Importantly, the Board's conclusions on non-obviousness under § 103 are relevant to patent-eligibility under § 101, as are the supporting documents. *See Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1347 (Fed. Cir. 2015) ("[P]recedent illustrates that pragmatic analysis of § 101 is facilitated by considerations analogous to those of §§ 102 and 103 as applied to the particular case.").

Illumina submitted a Patent Owner's Response that in detail explains the inventive concept and why the claimed subject matter is not conventional or routine in the prior art. That response includes over 50 pages of successful analysis based on *evidence* describing the inventive concepts and explaining why Natera's contentions as to what is conventional and routine are wrong based on an expert analysis of the literature. For example, Natera contends *Fan* and *Chiu*, two references that Natera relied on in the IPR and again relies on in this case, show that a reliable fetal aneuploidy test using a maternal blood sample was common at the time of the invention of the '831 Patent. However, as the Response details, *Fan* states that a prenatal test for detecting fetal aneuploidy from a maternal blood sample was "a challenging problem because fetal DNA constitutes a small percentage of total DNA in maternal blood" and *Chiu* likewise states detecting fetal DNA in

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maternal blood is a “considerable challenge.” The *Lo* reference Natera relies upon further corroborates these points in stating “[t]he detection of fetal chromosomal aneuploidies using plasma nucleic acids represents a considerable challenge in the field.” The Response then explains in-depth why Natera’s contentions regarding what was conventional and routine and within the knowledge of one of ordinary skill in the art in the field at the time of the invention are wrong.

The problem with Natera’s demand for a comprehensive response at this early stage of discovery is that the issues of prior art conventionality and inventive improvement are appropriately the subject of expert discovery. If Natera is asking Illumina to catalog evidence that will support expert opinions beyond the IPR proceedings and the patent documents, such a request is premature until the main fact discovery is conducted.

It is unreasonable for Natera to expect Illumina to identify evidence from Natera or third parties until discovery is conducted. Illumina has already directed Natera to its own patent filings as one rich source of evidence about technological improvement for example. The named inventors of the ’831 Patent are third parties who have not been deposed yet. It is thus premature to identify inventor evidence. Insofar as Illumina is collecting evidence to support expert opinion on inventiveness and what was routine in the prior art, the disclosure of that evidence is premature too.

As Illumina has explained to Natera, it intends to supplement its response after the completion of relevant fact discovery in this case and before expert discovery. In the past few weeks, Natera has produced nearly 350,000 pages of ESI custodial documents—more than doubling the size of its document production—comprising documents expected to be relevant to this issue. Likewise, Illumina has produced nearly 450,000 pages of ESI custodial documents—more than tripling the size of its document production—again comprising documents that might eventually be relevant to this issue depending on the expert phase. This discovery is only occurring now after Natera had the parties revise ESI custodians and engage in multiple rounds of amending search terms for several months that delayed production.

Further, depositions specific to ’831 Patent patent-eligibility have not occurred yet. In fact, only a single deposition has occurred in this case so far—that of an inventor on Natera’s ’592 Patent. Depositions for third-parties Drs. Yue-Jen (Jenny) Chuu and Richard Rava, the named inventors of the ’831 Patent, are forthcoming with the latter scheduled to be deposed on October 24. Drs. Chuu and Rava made their inventions while at Verinata many years ago. These inventors are in new careers and have not been associated with Illumina for many years.

As described above, Illumina has provided a sufficient response to this interrogatory and Natera’s request should be denied. Illumina intends to supplement its response after relevant fact discovery is taken and before the expert discovery phase when these issues can be more fully-developed.

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Respectfully submitted,

GIBSON, DUNN & CRUTCHER LLP

WEIL GOTSHAL & MANGES LLP

/s/ Tracey B. Davies

Tracey B. Davies

/s/ Derek C. Walter

Derek C. Walter

Tracey B. Davies (pro hac vice)
tdavies@gibsondunn.com
Mark Reiter (pro hac vice)
mreiter@gibsondunn.com
GIBSON, DUNN & CRUTCHER LLP
555 Mission Street, Suite 3000
San Francisco, CA 94105-0921
Telephone: 415.393.8200
Facsimile: 415.393.8306

Edward R. Reines (State Bar No. 135960)
Email: edward.reines@weil.com
Derek C. Walter (State Bar No. 246322)
Email: derek.walter@weil.com
WEIL GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
Tel: 650-802-3000
Fax: 650-802-3100

Attorneys for Defendant and Counterclaim-
Plaintiff, NATERA, INC.

Attorneys for Plaintiff and Counterclaim-
Defendant, ILLUMINA, INC.